REMARKS

The Office Action mailed on August 8, 2009, has been reviewed and the comments of the Examiner carefully considered. Claims 1-8 are pending and currently stand rejected. Claim 1 has been amended herein. No new matter has been added by way of this amended.

Rejections Under 35 U.S.C. § 103

Claims 1-8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cheong (US 6,326,410) in view of Webster (US 4,664,662). Regarding independent claim 1, the Examiner alleged that although Cheong does not explicitly teach treating the foamed product with a dispersion of therapeutic agent prior to drying, Cheong contemplates such treatment by teaching that "the foams of the invention may also include topical medicaments and antiseptics…as well as other therapeutically useful additives" (col. 3, line 65 – col. 4, line 3). Further, the Examiner alleged that treatment of polyurethane foams with therapeutic agents is well-known in the art as Webster teaches polyurethane foam wound dressings may contain therapeutic agents and that "[t]he physiologically active component may be incorporated into the foam during the process for manufacturing the foam or just prior to use by soaking in a solution of the components" (col. 8, lines 8-11). Thus, the Examiner alleged that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to treat the polyurethane foams of Cheong with a dispersion of a therapeutic agent per the teachings of Webster to provide a polyurethane wound dressing material with a therapeutic agent. Applicants respectfully disagree.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all claim limitations. MPEP § 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Applicants respectfully submit that neither Cheong nor Webster, alone or in combination, teaches, suggests, or otherwise discloses all limitations of the instant invention.

Regarding Cheong, as the Examiner admitted, "Cheong does not explicitly teach treating the foamed product with a dispersion of therapeutic agent prior to drying".

Webster cannot cure the deficiencies of Cheong. Webster discloses a foam wherein the "physiologically active component may be incorporated into the foam during the process of manufacturing the foam or just prior to use by soaking in a solution of the components". Webster, however, provides no teaching, nor any guidance as to why the skilled artisan would select one method over the other. In fact, Webster provides no teaching, suggestion or motivation whatsoever for the skilled artisan to select one method of treatment of foam over the other. Cheong, on the other hand, provides a detailed description describing the art-accepted addition of a therapeutic agent to a pre-foam mixture, as well as experimental examples directed to how the skilled artisan would prepare various foams. Thus, even if the cited references were combined in the manner suggested by the Examiner, one of ordinary skill in the art would not arrive at the claimed treated foamed product, because the skilled artisan would not have any motivation, and therefore, no reasonable expectation of success, in arriving at the presently-claimed invention.

The foamed product of applicants' instant invention is treated post-manufacturing by a dispersion of a therapeutic agent, dried, and subsequently packaged and shipped for use. Thus, Webster does not teach, suggest, or otherwise disclose the claimed method of treating the foamed product with a dispersion of a therapeutic agent and drying the treated foamed product.

Because the method of the instant invention comprises treating the foamed product with a dispersion of a therapeutic agent and drying – *i.e.*, oven drying or freeze drying – the treated foamed product that the polyurethane foams of the claimed invention, surprisingly and unexpectedly, sustained release behavior superior to that of polyurethane foams that have been medicated by incorporating the medicament into the foaming polyurethane mixture (*see, e.g.*, page 2, lines 16-22; page 9, lines 16-19; page 10, lines 8-14; Figure 1; Experimental Example 2). Claim 1 has been amended herein to reflect this unexpected result.

Procedure 1 and Figure 1 of the instant specification illustrate one example wherein the sustained release of chlorhexidine gluconate (CHG) from the oven-dried and freeze-dried post-treated foamed materials of the claimed invention was compared to medicated foams made by incorporating CHG into the reaction mixture, and can be seen to provide a manifold sustained release of the CHG using UV/Visible spectrophotometer. At 25 hours, for example, the oven-dried and freeze-dried post-treated foamed materials of applicants' instant invention contain, respectively, approximately 9 mg/ml and 8.5 mg/ml of chlorhexidine compared to the 3.5 mg/ml of the prior art medicated foams. Even more surprising and unexpected, at 75 and 225 hours, the post-treated foamed materials of applicants' instant invention still contain approximately 4.5 mg/ml of the therapeutic agent while the prior art foams only contain less than 1 mg/ml. This clearly indicates superior sustained release behavior.

The Office Action contends that the results are "expected", as the concentration of therapeutic agent used in the two separate preparation methods differs. However, the skilled artisan would understand that adding therapeutic agent directly to a reaction mixture provides substantially greater therapeutic agent for incorporation into the foam structure, as the agent in present throughout the mixture. In contrast, when treating a previously-foamed product with a therapeutic agent, the therapeutic agent does not have access to as much of the foam product, as the foam has already cured (or begun to cure). For example, treatment of a previously-formed foam product does not necessarily allow ready access of the therapeutic agent to the interior spaces of the foamed product (i.e., a much longer period of time may be required for such access to occur).

Furthermore, as set forth in Procedure 1 of Example 2, both foam products – that which was prepared by adding therapeutic agent directly to a reaction mixture, and that which was prepared by treating a previously-foamed product with a therapeutic agent – were soaked in a saline solution in order to determine long-term sustained release of therapeutic agent. It is clear from Figure 1 that the treated foam prepared by treating a previously-foamed product with a therapeutic agent has superior results when compared to the other sample. These results are unexpected. As set forth above, for example, treatment of a previously-formed foam product does not necessarily allow ready access of the therapeutic agent to the interior spaces of the foamed product (i.e., it may take much longer periods of time for such access to occur). Therefore, regardless of the concentration of active agent in which a pre-formed foam was

soaked, one would expect that any additional therapeutic agent existing on the surface of such a foam product would be released very rapidly into the saline solution, and as a result, that the long-term sustained release of therapeutic agent would be less than (or at best, perhaps equal to) the long-term sustained release of therapeutic agent from a foam product prepared by adding therapeutic agent directly to a reaction mixture. Such is not the case for the claimed invention, and this unexpected result is neither taught nor suggested by either reference cited in the Office Action.

As neither Cheong nor Webster, alone or in combination, discloses the claimed method of forming a polyurethane foam wherein the polyurethane foam is treated with a dispersion of a therapeutic agent after forming the foam and then followed by drying, further wherein the treated foamed product exhibits a sustained release of therapeutic agent greater than that of a similar foamed product in which the therapeutic agent was added by way of incorporation into the reaction mixture, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, Applicants submit that claims 2-8 are thereby allowable as written as depending from an allowable independent claim.

VIA ELECTRONIC FILING

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5037) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

DEBORAH ADDISON ET AL.

Date: December 3, 2009 By: _____

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